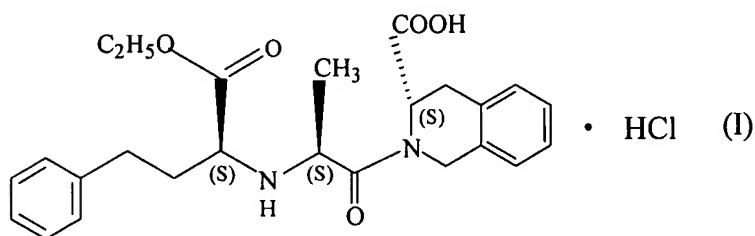


ABSTRACT

A novel crystalline form of quinapril hydrochloride of formula (I)



An amorphous form of quinapril hydrochloride substantially free of impurities, specially diketopiperazine compound, and conforming to pharmacopoeial specifications formed from the said novel crystalline form of quinapril hydrochloride of formula (I). The crystalline quinapril hydrochloride is in the form nitroalkane solvate in which the nitroalkane is nitromethane, nitroethane and nitropropane. Each such nitroalkane solvate having particular characteristic X- ray diffraction patterns. A process for preparation of amorphous form of quinapril hydrochloride, substantially free of impurities, specially diketopiperazine compound, and conforming to pharmacopoeial specifications, using the novel crystalline quinapril hydrochloride as an intermediate. The process involves obtaining free base compound of formula (V) by adjusting the pH of a solution of the benzyl ester maleate salt of quinapril of formula (V) between 7.5-8.5 in a mixture of water and an organic solvent; catalytic hydrogenation of this compound (V) in an alcoholic solvent in the presence of concentrated hydrochloric acid or hydrogen chloride dissolved in an alcoholic solvent and in the presence of catalytic amounts of Pd/C to obtain a residue containing formula (I); crystallization of the said residue by evaporating the alcoholic solvent from a nitroalkane solvent to give crystalline quinapril hydrochloride, associated with a solvate of the nitroalkane solvent, and drying the crystalline quinapril hydrochloride nitroalkane solvate at a temperature between 40⁰ C and 45⁰ C under vacuum to give amorphous quinapril hydrochloride of formula (I).